



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0381]

Generic Drug User Fee; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for enactment of a Generic Drug User Fee Act (GDUFA), which will authorize FDA to collect fees and use them for the process for the review of human generic drug applications and associated Type II Active Pharmaceutical Ingredient Drug Master Files (DMFs) and for conducting associated inspections for fiscal years (FYs) 2013-2017. New legislation would be required for FDA to establish and collect user fees under such a program. FDA and the regulated industry have developed a proposal for Congressional consideration. In the interest of transparency, and in an effort to voluntarily follow a process similar to the ones set forth in the Federal Food, Drug, and Cosmetic Act for FDA's other user fee programs, FDA is publishing the negotiated recommendations (the goals letter), holding a meeting at which the public may present its views on such recommendations, and providing an opportunity for the public to provide written comments on such recommendations.

DATE AND TIME: The public meeting will be held on December 19, 2011, from 10 a.m. to 5 p.m. Registration to attend the meeting must be received by December 12, 2011. The meeting will also be Web cast. See Section III. B. of this document for information on how to register for the meeting and Section III.C. on information about how to access the Web cast. Please submit

any comments that you plan to present at the public meeting to the docket by the date of the public meeting but note that written or electronic comments must be submitted by January 6, 2011.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2047, Silver Spring, MD 20993. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.fda.gov> and <http://www.regulations.gov> as soon as they are prepared after the public meeting (see Section III.C. of this document).

FOR FURTHER INFORMATION CONTACT:

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peter.beckerman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting to discuss proposed recommendations for the enactment of a GDUFA that would authorize FDA to collect user fees related to human generic drugs and use them for the process of the review of human generic drug applications and associated submissions, to conduct related inspections, and to engage in other related activities for FYs 2013 to 2017. New legislation is required for FDA to establish and collect user fees for generic drugs. In furtherance of such a program, FDA engaged in negotiations with three industry trade associations over aspects of a joint proposal for a generic drug user fee program, including fees and performance goals, from February through September 2011. The Agency held four prior public meetings on the topic before and during this process, posted meeting minutes after each negotiation session as well as posting other related materials, held a public docket open during the negotiation, and considered all comments that were submitted.

FDA and industry were able to reach agreement on a GDUFA program that, if enacted, is expected to place FDA's generic drug program on a sound financial footing and would further the fundamental interests of safety, access, and transparency. The GDUFA proposal that resulted from this process is focused on three key aims:

- **Safety:** To ensure that industry participants, foreign or domestic, who participate in the U.S. generic drug system are held to consistent high quality standards and are inspected biennially, using a risk-based approach, with foreign and domestic parity.
- **Access:** To expedite the availability of low-cost, high-quality generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments and supplements, increasing predictability, and timeliness in the review process.
- **Transparency:** To enhance FDA's ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs and associated active pharmaceutical ingredients and improving FDA's communications and feedback with industry in order to expedite product access.

Generic drugs play a critical role in providing more affordable, therapeutically equivalent medicine, and the GDUFA program is designed to keep individual fee amounts as low as possible to supplement appropriated funding to ensure that consumers continue to receive the significant benefits offered by generic drugs. Generic drugs provided more than \$824 billion dollars in savings to the nation's health care system in the last decade alone. The additional resources called for under the agreement, an inflation-adjusted \$299 million annually for each of

the 5 years of the program, will provide FDA with the ability to perform critical program functions that could not otherwise occur. This program is not expected to add significantly to the cost of generic drugs: Given that a reported 3.99 billion retail prescriptions per year were dispensed in the United States in 2010 and assuming that 78 percent of these prescriptions were filled by generic drugs, it equates to less than a dime per prescription for the average cost of a prescription filled by a generic drug in the United States. Moreover, with the adoption of user fees and the associated savings in development time, the overall expense of bringing a product to market may decline and result in reduced costs.

In addition to the public health benefits, the proposed program is expected to provide significant value to companies, and in particular to small companies and first time entrants in the generic market, who will benefit significantly from the certainty associated with performance review metrics that offer the potential to dramatically reduce the time needed to commercialize a generic drug when compared to pre-GDUFA review times.

Because FDA remains interested in hearing from nonaffiliated companies in addition to patient and consumer stakeholders, the Agency is holding this final public meeting prior to providing recommendations to Congress. The meeting will provide an explanation of the negotiated joint recommendations and provide an opportunity for additional stakeholder reaction and input.

II. The Proposed GDUFA Program

A. Recommendations

Key attributes of the proposed GDUFA Program, as negotiated, are memorialized in a goals letter that FDA has posted on its generic drug user fee Web page, which is accessible at <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>.

B. Summary of the Program

If enacted as negotiated, the program would provide FDA with additional funding for all aspects of the generic drug program in the amount of \$299 million per year, adjusted for inflation, for 5 years. With those additional user fee funds, FDA would agree to undertake a series of immediate program enhancements and performance goals. A nonexclusive list of major end goals for the program includes:

1. Application metrics that increase to an eventual year 5 goal of FDA reviewing and acting on 90 percent of complete electronic abbreviated new drug applications (ANDAs) within 10 months after the date of submission;

2. Backlog metrics of FDA reviewing and acting on 90 percent of all ANDAs, ANDA amendments, and ANDA prior approval supplements pending on October 1, 2012, by the end of FY 2017; and

3. Current good manufacturing practice (CGMP) inspection metrics under which FDA will conduct risk-adjusted biennial CGMP inspections of generic active pharmaceutical ingredient (API) and generic finished dosage form (FDF) manufacturers with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017.

Many additional, and interim, performance metrics and efficiency enhancements are set forth in the negotiated documents.

Under the program, fees would derive from two primary sources: Generic drug-related submissions and generic drug-related facilities. Submission fees would include fees for ANDAs and prior approval supplements, as well as for DMFs (for first reference only, as DMFs may be referenced multiple times by different sponsors). Facility fees would include fees for facilities that manufacture APIs for generic drugs as well and facilities that manufacture generic FDFs. In

the first year of the program, there would also be a fee assessed for applications that are pending on October 1, 2012, the so-called “backlog”.

As under the prescription drug user fee act (PDUFA), individual fee amounts would be set annually, with the total annual revenue provided by the user fee specified in statute. Of the total generic drug user fee revenue, 80 percent would be provided by the FDF manufacturers and 20 percent by API manufacturers. Additionally, 70 percent of the overall GDUFA revenue would be generated by facility fees and 30 percent would be generated by submission fees; though in the first year those splits will be slightly different because of the one-time backlog fee.

While it is not possible to provide actual individual fee amounts until such fees are set by a Federal Register notice, it is expected that individual GDUFA fees will be orders of magnitude less than PDUFA fees, a factor due to the larger fee paying base in GDUFA. In negotiating the program, FDA was cognizant that generic drugs are a tremendous public health success story, responsible for saving \$824 billion over the last decade. Consequently, the Agency worked to achieve a program that would not appreciably add to the cost of generic drugs, change the structure of the industry, or advantage any particular industry sector, regardless of size or location.

The program, as negotiated, is aimed at putting FDA’s generic drugs program on a firm financial footing and providing additive resources necessary to assure timely access to safe, high-quality, affordable generic drugs.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this notice, we are announcing a public meeting to update stakeholders and hear stakeholder views on the negotiated proposal for a generic drug user fee program. We will

conduct the meeting on December 19, 2011, from 10 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2047, Silver Spring, MD 20993. In general, the meeting format will include a presentation by FDA and presentations by stakeholders and members of the public who have registered in advance to present at the meeting. The amount of time available for presentations will be determined by the number of people who register to make a presentation. We will also provide an opportunity for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of this initiative. Accordingly, the presentations should focus on process and funding issues, and reactions to the GDUFA recommendations, and not focus on policy.

B. How Do You Register for the Meeting or Submit Comments?

If you wish to attend and/or present at the meeting, please register by email to GDUFA_Meeting4@fda.hhs.gov by December 12, 2011. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization, as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early. If you need special accommodations because of disability, please contact Mari Long or Peter Beckerman (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

In addition, any person may submit written or electronic comments to the Division of Dockets Management (see ADDRESSES). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration, all comments must be received by January 6, 2012. Submission of comments prior to the meeting is strongly encouraged.

C. Will the Meeting Be Web Cast?

For those unable to attend in person, FDA will Web cast and provide a telephone audio link to the meeting. To join the Web meeting, please go to <https://collaboration.fda.gov/gdufa/>. For audio, please call 301-796-2700 and enter participant code 121947. If you have never attended a Connect Pro meeting before, you may wish to test your connection by going to: https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.

D. Will Meeting Transcripts Be Available?

Please be advised that as soon as a transcript is available it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be made available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM)-1029, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: December 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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